DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV - 4 1999

Bryan J. Simmons
Hershey Foods Corporation
Law Department
100 Crystal A Drive
Hershey, Pennsylvania 17033-08 10

Dear Mr. Simmons:

This is in response to your letter of September 23, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your submission also states that Hershey Foods Corporation is marketing the product **"LUDEN'S Throat Drops/Herbal Supplement"** as a dietary supplement. This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 32 1 (ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(l)(B)(I) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

This product is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons. Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

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> The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(l)(B)(I) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(l)(B)(I) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product taken orally, but that delivers its contents only to the mouth or throat, is not subject to regulation as a dietary supplement because it is not "intended for ingestion." That your product is intended to deliver its contents prior to introduction into the gastrointestinal tract to exert its effect is evidenced by the statement of identity for the product that describes it as "throat drops."

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Philadelphia District Office, Office of Compliance, HFR-MA 140

c c :
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file, r/f)
HFS-450 (r/f, file)
HFD-3 10 (B Williams)
HFD-3 14 (Aronson)
HFS-605 (Bowers)
HFV-228 (Betz)
GCF- 1 (Dorsey, Barnett, Nickerson)
f/t:HFS-456:rjm:9/30/99:docname:67384.adv:disc41

Hershey Foods

BRYAN J. SIMMONS
Senior Counsel

Hershey Foods Corporation
Law Department
100 Crystal A Drive
Hershey, Pennsylvania 17033-0810
Direct Dial: (717) 534-7540
Telefax: (717) 534-7549

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September 23, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c St. SW
Washington, DC 20204

Re: Food, Drug and Cosmetic Act Section 403(r)(6)
Dietary Supplement Notification for LUDEN'S Throat Drops/
Herbal Echinacea Supplement

Dear Sir or Madam:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and 21 CFR 101.93, please be advised that Hershey Foods Corporation has commenced marketing LUDEN'S Throat Drops/Herbal Supplement. The product contains echinacea, rosehips and vitamin C, and the label bears the following statement:

"Supports the body's natural defense system"

I hereby certify that the information contained in this notice is complete and accurate, and Hershey Foods Corporation has substantiation that the above statement is truthful and not misleading.

Respectfully submitted,

Bryan J. Simmons

BJS:dlk

Enclosures (original and two copies)

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